UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MARYL GOLDIS-WELLER	§	
	§	
PLAINTIFF,	§	
	§	
V.	§	
	§	**Civil Action No. 5-21-cv-1222**
KONINKLIJKE PHILIPS N.V.;	§	
PHILIPS NORTH AMERICA LLC;	§	
PHILIPS HOLDING USA, INC.; and	§	**JURY DEMAND**
PHILIPS RS NORTH AMERICA LLC;	§	
	§	
DEFENDANTS.	§	

PLAINTIFF'S ORIGINAL COMPLAINT

Maryl Goldis-Weller, by and through the undersigned counsel, alleges as follows:

THE PARTIES

1. Plaintiff Maryl Goldis-Weller is an adult resident and citizen of San Antonio, Texas. San Antonio is located within Bexar County.

2. Plaintiff has resided as a citizen in San Antonio, Texas since approximately 2017. On or around late 2018, Plaintiff was prescribed and purchased the Philips Dream Station, while a resident of San Antonio, Texas. The entirety of her use of the subject device occurred in Texas.

3. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips NA and Philips RS. Royal Philips can be served with process via the *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or*

Commercial Matters ("Hague Service Convention"). Defendant Royal Phillips is subject to the jurisdiction and venue of this Court.

4. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is PHUSA, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA may be served through its registered agent at, Corporation Service Company - Lawyers Incorporating Service Company 211 E. 7th Street, Suite 620, Austin, TX 78701-3218.

5. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSA may be served through its registered agent at, Corporation Service Company - Lawyers Incorporating Service Company 211 E. 7th Street, Suite 620, Austin, TX 78701-3218.

6. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS may be served through its registered agent, Corporation Service Company - Lawyers Incorporating Service Company 211 E. 7th Street, Suite 620, Austin, TX 78701-3218.

7. Royal Philips, Philips NA, PHUSA, and Philips RS are hereinafter collectively referred to as "Philips" or the "Defendants."

JURISDICTION AND VENUE

8. At all times relevant hereto, Defendants created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed, supplied, and/or sold devices for the treatment of sleep apnea. This includes the subject device prescribed to and purchased by the Plaintiff at issue in this lawsuit.

9. At all times relevant hereto, Defendants were the mere alter ego or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to subsist. Defendants operated as a single enterprise, equipollently controlled each other's business affairs, commingled their assets, disregarded corporate formalities, and used each other as a corporate shield to vanquish equity, perpetuate fraud and eschew contractual and/or tort liability.

10. At all times relevant hereto, Defendants operated as agents of one another, working in concert to design, manufacture, promote, advertise, and sell devices for the treatment of obstructive sleep apnea, including the subject device. As part of a collaborative undertaking for profit, Defendants united their property and labor, with rights of mutual control over each other, rendering them jointly liable to Plaintiff.

11. Defendants regularly transact business in Texas that includes marketing, and selling devices for the treatment of respiratory issues, including obstructive sleep apnea, derive substantial revenue from their business transactions in Texas, and have intentionally taken advantage of the privilege of doing business in Texas.

12. Defendants facilitated the shipping of the subject device with the reasonable expectation that the devices would be marketed and sold in Texas.

13. Defendants possess business entities in Texas sufficing as "minimum contacts," that subject them to personal jurisdiction in Texas does not intrude traditional process of fair play and substantial justice.

14. As detailed below, Plaintiff was prescribed the subject device, bought the subject device, and suffered injuries within Bexar County, Texas, from use of the subject device that Defendants negligently designed and/or manufactured, marketed, and sold in Texas and outside of Texas. Thus, Defendants committed a tort either in Texas or outside of Texas that caused injuries in Texas, and the court has personal jurisdiction over Defendants under Texas Long Arm Statute, Tex. Civ. Prac. & Rem. Code § 17.042.

15. This Court has personal jurisdiction over Philips NA, PHUSA, and Philips RS because of their systematic and continuous contacts with Texas as well as their maintenance of registered agent for service of process in Texas.

16. This Court has personal jurisdiction over Royal Philips because of its systematic and continuous contacts with Texas.

17. This Court has original jurisdiction in this matter pursuant to 28 U.S.C. §1332(a)(1) and §1332(a)(2), as there is complete diversity between Plaintiff and Defendants and the amount in controversy exceeds $75,000.

18. There is complete diversity between Plaintiff and all of the members comprising Philips NA and Philips RS.

19. This Court is a proper venue for this civil action pursuant to 28 U.S.C § 1391(b)(2), as the event giving rise to the Plaintiff's claims occurred in San Antonio, Texas.

20. This Court's exercise of personal jurisdiction over Defendants comports with due process.

NATURE OF THE ACTION AND INTRODUCTION

21. This is a lawsuit seeking judgment against Defendants Koninklijke Phillips N.V., Philips North America LLC, and Philips RS North America LLC (collectively "Phillips" or "Defendants") for personal injuries and sequelae thereto sustained from Defendants' unreasonable dangerous product, the Philips Dream Station Device manufactured and sold by Defendants.

22. At all times relevant hereto, Defendants created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed, supplied, and/or sold the Philips Dream Station Device.

23. Philips manufactures and sells medical equipment products. These products include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are used in the treatment of sleep apnea, and ventilators, which treat respiratory failure.

24. On June 14, 2021, Phillips announced a recall of many of its CPAP/BiPAP machines and its ventilators because they suffer from a defect which could result in serious injury, permanent impairment, and may even be life-threatening.

25. These products contain polyester-based polyurethane ("PE-PUR") foam which is used to minimize the sound produced by the devices. According to Philips, this PE-PUR foam can deteriorate over time, causing it to break down. When the foam breaks down, small foam particles and gases can be inhaled or ingested through the use of the devices, which assist patients with respiration. The foam may emit volatile organic compounds, which when inhaled, can result in serious adverse health effects, including cancer.

GENERAL FACTS AND ALLEGATIONS

26. At all times relevant hereto, Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BiPAP devices as well as ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and other respiratory conditions, including sleep apnea.

27. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Recalled Devices, including the subject device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices *if* the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

28. CPAP and BiPAP machines and ventilators are all used to treat respiratory conditions that help assist the user in respiration.

29. Sleep apnea (including obstructive sleep apnea) is a common diagnosis that is treated by the use of CPAP and BiPAP machines.

30. Obstructive sleep apnea is a disorder that occurs when the muscles in the back of your throat relax to the point that they disrupt normal breathing. When the muscles relax, the airway is hindered, blocking it. This is a form of apnea, and these occurrences are called "apneas." Symptoms can include excessive daytime sleepiness, observed episodes of stopped breathing during sleep, abrupt awakenings accompanied by gasping or choking, high blood pressure, and mood changes such as depression or irritability. Serious cases can lead to hypertension, heart

attack or stroke. Obstructive sleep apnea affects between two and nine percent[1] of adults in the United States; however, many cases are said to go undiagnosed.

31. A common and widely used nonsurgical treatment for obstructive sleep apnea is CPAP therapy. CPAP therapy consists of the use a CPAP device, also known as continuous positive airway pressure device. The device delivers a constant flow of air through a mask that is placed over the nose and mouth, which assists in maintaining steady breathing while sleeping.

32. BiPAP machines are a similar sub-class of machines that treat sleep apnea. Unlike CPAP machines, BiPAP machines use two different pressures to mimic inhaling and exhaling rather than the single continuous level of pressurized air delivered by a CPAP device.

33. CPAP and BiPAP machines both consist of a main unit which connects to a facemask via an air hose. They are expected to be used every night in order to properly treat the symptoms associated with sleep apnea.

PHILIPS RECALL OF SLEEP & RESPIRATORY CARE DEVICES

34. On April 26, 2021, less than two weeks after it announced the launch of the second generation CPAP device, Philips disclosed in its Quarterly Report for Q1 2021 that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used and installed into several CPAP and BiPAP respirators to minimize noise, posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."[2]

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[1] Strohl, Kingman P, et al. "Obstructive Sleep Apnea - Pulmonary Disorders." MSD Manual Professional Edition, MSD Manuals, Sept. 2020, www.msdmanuals.com/professional/pulmonary-disorders/sleep-apnea/obstructive-sleep-apnea (last visited Dec. 9, 2021).

[2] *First Quarter Results*, PHILIPS (Apr. 26 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (last accessed Dec. 9, 2021)

35. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices.[3]

36. According to Philips, this PE-PUR foam can deteriorate over time, causing it to break down. When the foam breaks down, small foam particles and gases can be inhaled or ingested through the use of the devices which assist patients with respiration. The foam may emit volatile organic compounds, which when inhaled, can result in a wide range of potential patient impact, from transient potential injuries, worsened symptoms and/or complications, as serious life- threatening injury.

37. Philips disclosed in their June 14th recall notice that the PE-PUR foam installed in the recalled devices puts the recalled device users at risk of suffering from the following health harms: "Particulate exposure can cause headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."[4]

38. On June 14, 2021, the same day as the recall notice for the subject device, Philips also issued a brief report titled "Clinical Information for Physicians." In this report, Philips disclosed that "lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including: Toluene Diamine, Toluene Diisocyanate, Diethylene glycol."[5] Additionally,

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[3] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (last accessed Dec. 8, 2021)

[4] Philips issues recall notification, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-%20w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-%20health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last accessed Dec. 9, 2021).

[5] Sleep and Respiratory Care update, Clinical information for physicians, PHILIPS (June 14, 2021), https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf?_ga=2.43039205.1759564883.162500670621213032 6.1624473291&_gl=1*2nhu1w*_ga*MjEyMTM

in the same report, Philips also disclosed that through testing performed by and for Philips, the presence of Volatile Organic Compounds (VOCs) was confirmed. These compounds may be emitted from the sound abatement foam installed in the affected devices. "VOCs emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects. Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following: Dimethyl Diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-."

39. Defendants disclosed receiving complaints about the recalled devices, "representing 0.03 percent of those sold in 2020."[6] However, Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)." However, given how long ago the first of the Recalled Devices came to market, it is unlikely that Defendants only recently learned of these issues.

40. Philips disclosed that an estimated number of "between 3 million and 4 million" devices are subject to the recall.[7]

41. On July 8, 2021, Philips released a global supplemental clinical information document that was based on their own testing of the affected devices, stating that, "According to the analysis performed by Philips, the majority of particulates are of a size (>8 µm)..." "Smaller particulates (1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli." "During testing performed by an outside laboratory on lab degraded foam. The smallest particulate

wMzI2LjE2MjQ0NzMyOTE.*_ga_2NMXNNS6LE*MTYyNTE1MTQ3MC4xNi4xLjE2MjUxNTE1OTUuMTg. (last accessed Dec. 9, 2021).

[6] Associated Press, Philips recalls ventilators, sleep apnea machines due to health risks, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725 (last accessed Dec. 9, 2021)

[7] *Id.*

size identified was 2.69 µm."[8] The Environmental Protection Agency (EPA) notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases."[9]

42. On July 22, 2021, The FDA classified the recall as a Class I recall, the most serious type of recall and stated, "Use of these devices may cause serious injuries or death."[10]

43. Philips instructed users of the recalled CPAP and BiPAP devices to, "Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[11]

44. Philips instructed users of the recalled ventilator devices to, "NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[12]

45. All devices subject to the recall were disclosed as part of the June 14, 2021 recall notification. The list of affected Philips devices includes 18 CPAP, BiPAP, and Ventilator type devices:[13] Listed below are the affected devices:

a. Type: Continuous Ventilator, Minimum Ventilatory Support, Facility Use

1. Model: E30 (Emergency Use Authorization)

b. Type: Continuous Ventilator, Non-life Supporting

[8] Respironics, P. (2021, July 8). *Sleep and Respiratory Care update Clinical information*. Retrieved Dec. 9, 2021.
[9] Environmental Protection Agency. (n.d.). EPA. Retrieved September 16, 2021, from https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm.
[10] Center for Devices and Radiological Health. (n.d.). Philips Respironics RECALLS Certain Ventilators, CPAP, AND BIPAP DEVIC. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and.
[11] Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2(last accessed Dec. 9, 2021)
[12] *Id.*
[13] *Id.*

i. Model: DreamStation, ASV

ii. Model: DreamStation, ST, AVAPS

iii. Model: SystemOne, ASV4

iv. Model: C Series, ASV, S/T, AVAP

v. Model: OmniLab Advanced Plus, In-lab Titration Device

c. Type: Non-continuous Ventilator

i. Model: SystemOne (Q series)

ii. Model: DreamStation

iii. Model: DreamStation GO

iv. Model: Dorma 400, 500

v. Model: REMStar SE Auto

d. Type: Mechanical Ventilators

i. Model: Trilogy 100

ii. Model: Trilogy 200

iii. Model: Garbin Plus, Aeris, LifeVent

e. Type: Continuous Ventilator, Minimum Ventilatory Support, Facility Use

i. Model: A-Series BiPAP Hybrid A30

ii. Model: A-Series BiPAP V30 Auto

f. Type: Continuous Ventilator, Non-life Supporting

i. Model: A-Series BiPAP A40

ii. Model: A-Series BiPAP A30

FACTUAL ALLEGATIONS SPECIFIC TO THE PLAINTIFF

45. On or around 1992 and a second Dream Station in approximately 2018, Plaintiff was prescribed and purchased a Philips Dream Station Device. The subject device prescribed for and purchased by Plaintiff was one of the Recalled Devices.

46. At the time Plaintiff was prescribed the use of and purchased the subject device, she was a resident and citizen of San Antonio, Texas.

47. Since 2020, Plaintiff used the subject device daily to treat her sleep apnea.

48. At all times Plaintiff used the subject device, he used the subject device in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

49. At all times Plaintiff used the subject device, he did so for the purpose for which it was marketed, designed, and intended.

50. At all times Plaintiff used the subject device, he did so in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

51. After, and as a result of using the subject device, Plaintiff has suffered personal injuries including without limitation cancerous tumors in her stomach. These injuries would not have occurred but for the defective nature of the subject device and/or Defendants' wrongful conduct.

53. Plaintiff's use of the subject device caused or significantly contributed to her development and progression of lung damage, which has permanently changed her life.

54. By reason of the foregoing, Plaintiff has had to undergo significant treatment, will be required to undergo significant treatment in the future, and now requires constant and

continuous medical monitoring and treatment due to the defective nature of the subject device and/or Defendants' wrongful conduct.

55. As a result of the aforesaid conduct and subject device manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was injured, resulting in severe mental and physical pain and suffering. Such injuries will result in some permanent disability to her person. As a result of such injuries, Plaintiff has suffered losses for which compensatory damages should be awarded.

COUNT I
Strict Products liability – Design Defect

56. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

57. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

58. The subject device is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The subject device is defective in design because it causes headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects. It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

59. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Defendants. Subject device was expected to and did reach Plaintiff and her physician

without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

60. The subject device was used for its intended purposes by Plaintiff and the subject device was not materially altered or modified prior to its use.

61. The subject device is defective in design because the PE-PUR foam comprising part of the device is subject to degradation by hydrolysis. These characteristics cause, among other problems, cancer, sarcoidosis, and cardiac injuries.

62. At or before the time the subject device was released on the market and/or sold to Plaintiff, Defendants could have designed the product to make it less prone to causing the above listed health harms, a technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the device.

63. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the subject device in a way as to make the risk of harm or injury outweigh any benefits.

64. Defendants knew or should have known that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew or should have known that patients for whom the Recalled Devices would be used, such as Plaintiff, could be and would be affected by the defective design and composition of the devices.

65. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective device which, when used in its intended or reasonably

foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

66. Plaintiff Maryl Goldis-Weller was proximately harmed by the design defects in the subject device as described above.

WHEREFORE, Plaintiff, Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

COUNT II
Strict Products Liability – Failure to Warn

67. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

68. At all times herein mentioned, Defendants designed, developed, researched, tested, and knew or should have known about significant sarcoidosis and cardiac impairment risks with subject device.

69. At all times herein mentioned, Defendants advertised, promoted, marketed, sold, and distributed the subject device that was used by the Plaintiff.

70. The subject device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

71. Defendants each had an independent duty and continuing duty to warn the medical community and Plaintiff's physicians about the significance of the risks of cancer and other health harms with the subject device.

72. Plaintiff used the subject device in a manner intended and foreseeable by Defendants.

73. The subject device was defective due to inadequate warnings because Defendants knew or should have known that the product created a significantly increased risk of sarcoidosis, among other health impacts, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

74. Defendants omitted and downplayed the significantly increased risks of sarcoidosis and other health risks with the subject device that Defendants knew or should have known from previous testing and research even prior to subject device's FDA approval.

75. The subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health issues.

76. If Defendants would have properly warned about the subject device's cancer risk and/or other health harms, no reasonable physician, including Plaintiff's physician, would have recommended or prescribed the subject device because the potential benefits of non-obstructive sleep are significantly outweighed by the risk of sarcoidosis and/or other harms.

77. Had Defendants reasonably provided adequate warnings of , such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, would have prescribed the subject device and no consumer, including Plaintiff, would have purchased and/or used the subject device.

78. Plaintiff Maryl Goldis-Weller was proximately harmed by the design defects in the subject device as described above.

WHEREFORE, Plaintiff, Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be

permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

COUNT III
Strict Liability – Manufacturing Defect

79. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

80. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

81. The subject device was expected to and did reach Plaintiff without a substantial change in its condition.

82. The finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

83. At all times relevant hereto, the Recalled Devices, including the subject device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury, including sarcoidosis.

84. The foreseeable risks of the subject device were known and could have been avoided.

85. At all times relevant hereto, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

86. At all times relevant hereto, Defendants actively deceived users that their use of the Recalled Devices posed safety risks that far outweighed any benefits.

87. Furthermore, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, sarcoidosis. Plaintiff and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, respiratory irritants and other deleterious components and contaminants when using the Recalled Devices.

88. Plaintiff Maryl Goldis-Weller was proximately harmed by the design defects in the subject device as described above.

COUNT IV Negligence - Design Defect

89. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

90. Each of the subject devices was expected to reach, and did reach, users and/or consumers, including Maryl Goldis-Weller without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

91. Under Texas products liability law, Defendants, Philips, owed Plaintiff Maryl Goldis-Weller a duty to exercise reasonable care in designing and testing the subject device.

92. Defendants, Philips designed the subject device for the purpose of helping treat respiratory disorders through positive airway pressure.

93. At all times material hereto, the subject devices were used in a manner intended and/or foreseeable to the Defendants.

94. A patient or consumer using the subject device would reasonably expect the device to be free of significant defects.

95. The subject device, as designed by the Defendants, releases chemicals and off gases particles, including Toluene Diamine, Toluene Diisocyanate, Diethylene glycol.

96. The subject device, as designed by the Defendants, directly transmits carcinogenic materials to patients during CPAP and/or BiPAP therapy.

97. The foreseeable risks of using the subject device, particularly respiratory illnesses up to and including death, significantly outweigh the benefits conferred upon patients using the subject device.

98. Reasonable alternative designs existed for the subject device which would have eliminated or reduced the risk of inhalation of carcinogenic materials and volatile organic compounds.

99. Reasonable and feasible alternative designs include, but are not limited to, RESMed, 3B Medical and Apex Medical.

100. The failure to use feasible, reasonable alternative designs that eliminate the release of chemicals and off gassed particles renders the subject device unreasonably unsafe.

101. Defendants knew or should have known that Philips Dream Station CPAP-BiPAP Devices were likely to release carcinogenic chemicals and volatile organic compounds.

102. Plaintiff's injuries were caused by Defendants' conduct as follows:

a. Failing to conduct adequate safety and efficacy testing before placing the subject device into the stream of commerce;

b. Failing to timely establish procedures for reviewing the design of the subject device after receiving information that patients were developing respiratory illnesses as a result of using the subject device;

c. Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the subject device before their implementation; and

d. Failing to design or redesign the subject device to eliminate or mitigate the release of carcinogenic chemicals and/or volatile organic compounds.

103. Plaintiff Maryl Goldis-Weller was proximately harmed by the design defects in the subject device as described above.

WHEREFORE, Plaintiff, Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

COUNT V
Negligence – Manufacturing Defect

104. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

105. The subject device was expected to reach, and did reach, users and/or consumers, including Plaintiff Maryl Goldis-Weller, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

106. Defendants manufactured the subject device for the purpose of helping treat respiratory disorders through positive airway pressure.

107. At all times material hereto, the subject device was used in a manner intended and/or foreseeable to the Defendants.

108. A reasonable patient or consumer of the subject device would expect that the device be free of significant defects.

109. The subject device, as manufactured by the Defendants, releases carcinogenic chemicals and/or volatile organic compounds. The subject device, as manufactured by the Defendants, directly releases carcinogenic chemicals and/or volatile organic compounds.

110. The foreseeable risks of using the subject device, particularly the risk of respiratory illnesses up to and including death, significantly outweigh the benefits conferred upon patients using the subject device.

111. Plaintiff Maryl Goldis-Weller's injuries were caused by Defendants' conduct as

follows:

a. Failing to timely establish procedures or practices to prevent the subject device from releasing carcinogenic chemicals and/or volatile organic compounds;

b. Manufacturing and selling the subject device in a state that would allow for the breakdown and release of carcinogenic chemicals and/or volatile organic compounds; and

c. Failing to ensure proper workmanship, materials and labeling for the subject device.

112. Plaintiff Maryl Goldis-Weller was proximately harmed by the manufacturing defects in the subject device as described above.

WHEREFORE, Plaintiff, Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

COUNT VI Negligence - Warnings Defects

113. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

114. The subject device was expected to reach, and did reach, users and/or consumers, including Plaintiff Maryl Goldis-Weller, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

115. Defendants owed Plaintiff Maryl Goldis-Weller a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the subject device.

116. Defendants marketed, advertised and promoted the subject device for the purpose of helping treat respiratory disorders through positive airway pressure.

117. At all times material hereto, the subject device was used in a manner intended and/or foreseeable to the Defendants.

118. A reasonable patient or consumer of the subject device would expect that the device be free of significant defects.

119. The subject device releases carcinogenic chemicals and volatile organic compounds, and directly transmits such chemicals and compounds to patients during airway pressure therapy.

120. Defendants knew or should have known that carcinogenic chemicals and volatile organic compounds were likely to be released from the subject device and could be spread to patients through the sound abatement foam.

121. The foreseeable risks of using the subject device, particularly severe respiratory disorders and/or death, significantly outweigh the benefits conferred upon patients using the subject device.

122. Plaintiff Maryl Goldis-Weller's cancer was caused by Defendants' conduct as follows:

a. Failing to warn patients like Plaintiff Maryl Goldis-Weller and/or purchasers of the subject device that the sound abatement foam broke down and released carcinogenic chemicals and volatile organic compounds and were unnecessarily transmitted into the users of subject device; and

b. Failing to timely notify known purchasers of the subject device that patients could be exposed to carcinogenic chemicals and volatile organic compounds;

123. Plaintiff Maryl Goldis-Weller was proximately harmed by the warnings defects in the subject device as described above.

WHEREFORE, Plaintiff Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

COUNT VII
Breach of Implied Warranty of Merchantability

124. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

125. Defendants marketed, advertised and promoted the subject device for the purpose of helping treat respiratory disorders through positive airway pressure.

126. The subject device sold by Defendant and used in Plaintiff Maryl Goldis-Weller's treatment of obstructive sleep apnea was subject to an implied warranty of merchantability.

127. Defendants warranted and represented that the subject device was merchantable and fit for the intended uses and that the device was otherwise safe in its design, manufacture, construction and operation for ordinary use.

128. Defendants breached these implied warranties regarding the subject device, including its component parts, in that the device was not merchantable and fit for the intended uses and were otherwise unsafe in its design, manufacture, construction and operation for ordinary use.

129. The subject device designed, marked and sold by Defendants was expected to reach, and did reach, users and/or consumers including Plaintiff Maryl Goldis-Weller, without substantial change in the defective unreasonably dangerous condition in which it was sold or distributed.

130. The Defendants breached the implied warranty as the subject device was defective at the time of the sale in that it was not fit to treat obstructive sleep apnea without releasing carcinogenic chemicals and/or volatile organic compounds in users using the subject device system.

131. Plaintiff Maryl Goldis-Weller, was proximately harmed by the breach of implied warranty of the Defendants as described above.

WHEREFORE, Plaintiff Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

COUNT VIII
Negligent Misrepresentation

136. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

137. The subject device is a product within the meaning of Texas products liability law.

138. Defendants designed, manufactured, marketed, advertised, promoted, and sold the subject device which was expected to reach, and did reach, users and/or consumers, including Plaintiff Maryl Goldis-Weller.

139. Defendants owed Plaintiff Maryl Goldis-Weller, her physicians, and health-care providers a duty to exercise reasonable care in labeling, marketing, advertising, promoting, distributing and/or selling the subject device.

140. Based upon information and belief, the Defendants supplied information to Plaintiff Maryl Goldis-Weller and health-care providers including, but not limited to, product labeling, and advertising and promotional materials.

141. The subject device releasing carcinogenic chemicals and/or volatile organic compounds.

142. Defendants knew or should have known that sound abatement foam could break down and release carcinogenic chemicals and volatile organic compounds into the users of subject device.

143. The information supplied by the Defendants misrepresented the safety of the subject device. The Defendants represented that the subject device should be replaced every five years because the air pressure emitted would decrease over time. The Defendants excluded information regarding release of carcinogenic chemicals and/or volatile organic compounds.

144. The Defendants intended for Plaintiff's physicians and health-care providers to rely upon these representations in their prescription practices.

145. Plaintiff's physicians and health-care providers relied upon these representations in deciding to purchase, prescribe and use the subject device.

146. At all times material, the subject device was used in a manner intended and/or foreseeable to the Defendants.

147. The Defendants failed to exercise reasonable care or competence in communicating these risks to Plaintiff Maryl Goldis-Weller and/or her health-care providers.

148. Plaintiff Maryl Goldis-Weller was proximately harmed by the negligent misrepresentations made by the Defendants as described above.

WHEREFORE, Plaintiff Maryl Goldis-Weller, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Texas, together with interest thereon, costs of suit and attorneys' fees.

PRAYER FOR RELIEF

Plaintiff Maryl Goldis-Weller requests the Court to enter judgment against the Defendants as follows:

a. An award to Plaintiff of compensatory and punitive damages, costs and reasonable attorneys' fees, as permitted by law;

b. Pain and suffering (past and future);

c. Wage loss (past and future);

d. Loss of earnings and loss of earning capacity;

e. Mental anguish and distress (past and future);

f. Disfigurement (past and future);

g. Physical impairment (past and future);

h. Costs and expenses incurred in this litigation, including but not limited to expert fees and reasonable attorney's fees;

i. Any and all applicable statutory and civil penalties, as allowed by law;

j. Punitive or exemplary damages in such amounts as may be proven at trial;

k. An award of pre-judgment and post-judgment interest, as provided by law;

l. Leave to amend this Complaint to conform to the evidence produced at trial; and

m. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

DATED: December 10, 2021

Respectfully submitted,

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